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Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER CL/V-31010A
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
			10/019134
INTERNATIONAL APPLICATION NO. EP 00/05835	INTERNATIONAL FILING DATE 23 June 2000 (23.06.00)	PRIORITY DATE CLAIMED 25 June 1999 (25.06.99)	
TITLE OF INVENTION UV ILLUMINATION DEVICE			
APPLICANT(S) FOR DO/EO/US HEINRICH ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau. (See Form PCT/IB/308)
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: Priority Document # 99112256.1 Filed 25.06.99

U.S. APPLICATION NO. (if known, see 37 CFR 1.51) 10/019134		INTERNATIONAL APPLICATION NO. EP 00/05835		ATTORNEY'S DOCKET NUMBER CL/V-31010A	
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17. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):				CALCULATIONS PTO USE ONLY	
Search Report has been prepared by the EPO or JPO				\$890	
International preliminary examination fee paid to USPTO (37 CFR 1.482)				\$710	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).				\$740	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.				\$1,040	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).				\$100	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 890	
Surcharge of \$130 for furnishing the oath of declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	16	- 20 =	X \$ 18	\$	
Independent claims	1	- 3 =	X \$ 84	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 280	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 890	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
SUBTOTAL =				\$ 890	
Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 890	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property				\$ 0	
TOTAL FEES ENCLOSED =				\$ 890	
				Amount to be:	\$
				refunded	
				charged	\$

a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.

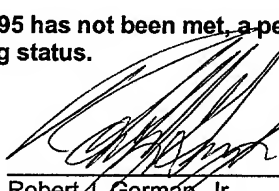
b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis Corporation in the amount of \$890 to cover the above fees. A duplicate copy of this form is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis Corporation.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to the address associated with
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3/parts

UV illumination device

The invention relates to a method and device for crosslinking a biocompatible, polymerisable material in order to produce an ophthalmic moulding, especially an ophthalmic lens, particularly a contact lens.

Contact lenses, which are to be manufactured economically in large unit numbers, are preferably manufactured by the so-called mould or full-mould process. In these processes, the lenses are manufactured into their final shape between two mould halves, so that there is no need to subsequently finish the surfaces of the lenses, nor to finish the edges. Mould processes are described for example in PCT patent application no. WO/87/04390 or in EP-A 0 367.513.

The contact lenses produced in this manner are moulded parts having little mechanical stability and a water content of more than 60 % by weight. After manufacture, the lens is inspected, then packed and subjected to heat sterilisation at 121°C in an autoclave.

In these known mould processes, the geometry of the contact lenses to be manufactured is defined by the mould cavity. The edge of the contact lens is likewise formed by the mould which normally consists of two mould halves. The geometry of the edge is defined by the contour of the two mould halves in the area in which they make contact.

To manufacture a contact lens, first of all a certain amount of a flowable starting material is placed in the female mould half. Afterwards, the mould is closed by placing the male mould half thereon. Normally, a surplus of starting material is used, so that, when the mould is closed, the excess amount is expelled out into an overflow area adjacent to the mould cavity. The subsequent polymerisation or crosslinking of the starting material takes place by radiation with UV light, or by heat action, or by another non-thermal method.

In US-A-5,508,317, a new contact lens material is described, which represents an important improvement in the chemistry of polymerisable starting materials for the manufacture of contact lenses. The patent discloses a water-soluble composition of a prepolymer, which is filled into the mould cavity and then crosslinked photochemically. Since the prepolymer has several crosslinkable groups, the crosslinking is of high quality, so that a finished lens of

optical quality can be produced within a few seconds, without the necessity for subsequent extraction or finishing steps. Owing to the improved chemistry of the starting material as illustrated in the patent, contact lenses can be produced at considerably lower cost, so that in this way it is possible to produce disposable lenses that are used only once.

EP-A-0 637 490 describes a process by means of which a further improvement may be obtained in the preparation process of contact lenses with the prepolymer described in US-A-5,508,317. Here, the material is filled into a mould comprising two halves, whereby the two mould halves do not touch, but a thin circular gap is located between them. The gap is linked to the mould cavity, so that surplus lens material can flow away into the gap. Instead of the polypropylene moulds that may be used only once, reusable quartz/glass moulds may be used. Because of the water-soluble basic chemistry, after a lens has been produced, the uncrosslinked prepolymer and other residues can be removed from the moulds rapidly and effectively with water, and the moulds dried in the air. In this way, high precision of the lens shaping may also be achieved. Crosslinking of the prepolymer takes place by radiation especially with UV light, whereby radiation is restricted to the mould cavity by a chromium screen. In this way, only the material in the mould cavity is crosslinked, so that there is high reproducibility of the edges of the lens without closing the two polypropylene mould halves. The uncrosslinked shaded-off prepolymer solution can be easily washed away from the shaped, crosslinked lens with water.

However, during radiation with conventional UV lamps, there are frequently problems concerning homogeneity of radiation, especially when using glass casting moulds. Owing to the uneven illumination of the mould cavity, the moulding may have a varying degree of crosslinking, which has a negative effect on the stability of the moulding. The edges in particular are frequently insufficiently polymerised, so that the borders of the moulding are not clearly defined.

The invention is concerned with the problem of further improving the crosslinking process for ophthalmic mouldings consisting of biocompatible polymerisable materials, especially for contact lenses, in order to ensure constant quality of the mouldings.

The invention solves this problem with the features indicated in claim 1. As far as further essential embodiments of the process according to the invention and of the device according to the invention are concerned, reference is made to the dependent claims.

By coupling the UV light into the mould cavity using optical fibres, homogeneous illumination is assured, together with high intensity of radiation of the mould cavity. By attaching a number of optical fibres to an ultraviolet lamp, an ultraviolet lamp can be used to crosslink a number of casting moulds, whereupon a very high intensity of illumination can be attained in an efficient manner, enabling rapid polymerisation of the filled moulding material to take place.

Further details and advantages of the invention may be seen from the description that follows and the drawing. In the drawing,

Fig.1 shows a schematic illustration of an embodiment of a UV illuminating device according to the invention;

Fig.2 shows a schematic illustration of a means of coupling the UV light into an optical fibre;

Fig. 3 shows a schematic illustration of the exposure of a casting mould by an optical fibre.

The UV illuminating device 1 illustrated schematically in fig. 1 is preferably mounted in a housing 16 illustrated only schematically here, and consists of a UV lamp 2 and several, advantageously 5 to 50, preferably 10 to 30 optical fibres 3, which surround the UV lamp 2 and are each fixed by a holder 4. The UV lamp 2 in question is suitably a mercury lamp, especially a doped medium pressure mercury lamp, whereby a medium pressure lamp HPA 2020 from Philips or a comparable medium pressure lamp from the company Heraeus can be used for example. The optical fibres 3 conveniently have a length of 0.3 to 2 m and are advantageously formed as liquid optical fibres, since these are particularly well suited to the transmission of UV light. Liquid optical fibres are notable for their high UV transmission, their more homogeneous distribution of intensity of the emerging light rays compared with quartz fibre bundles, and their higher usable cross-sectional area given the same diameter. The UV lamp 2 can be suitably mounted on a quick-change cradle (not illustrated) to enable the lamp 2 to be exchanged easily. The emission spectrum of the UV lamp 2 advantageously has a high UV intensity in the wavelength range 280 - 360 nm, since in this range various types of

photoinitiators that can be used in lens material can be activated, for example Irgacure 2050. Due in particular to the radial arrangement of the optical fibres 3 in relation to the longitudinal axis of the UV lamp 2, a high proportion of the radiation emitting from the UV lamp 2 can be coupled into the optical fibres 3 and thus used for crosslinking. The maximum number of optical fibres that can be used is dependent on the diameter of the UV lamp 2 and the distance to the UV lamp. In addition, there is advantageously a sensor 5, which measures the intensity of UV radiation. It is located near to the UV lamp 2. The measurement is passed on to a regulating unit 6 which compares the measured intensity of radiation with a theoretical value and regulates the current intensity I to keep it constant. In addition, a cool stream of air 7 is provided to cool the UV lamp 2. It is passed from the cold components over the hot components by means of an appropriate construction of the housing 16, or by a ventilator 22, respectively. The air stream is controlled by one or more temperature sensors 8 which measure the temperature inside the housing. The cool air stream ensures that the UV lamp 2 burns at an optimum temperature and that the components in the housing of the lamp do not become overheated. In this way, constant operating conditions are assured, which also prolong the life of the UV lamp 2.

The coupling of UV light into the optical fibres 3 is illustrated in more detail in fig. 2. In order to couple a high intensity of radiation into the optical fibres, a minimum distance to the UV lamp is required, advantageously ca. 1 mm. Since the surface of the UV lamp reaches a temperature or more than 800°C, direct coupling to a liquid optical fibre is impossible owing to its temperature sensitivity. Therefore, the light emitting from the UV lamp is firstly coupled into a quartz rod 9, the diameter of which is co-ordinated with that of the optical fibre 3. The length of the quartz rod 9 depends on the effectiveness of cooling produced by the stream of air. In a first approximation, the length of the quartz rod 9 has no affect on the light intensity that can be coupled into the optical fibres 3. Depending on the design of the lamp, the length of the quartz rod 9 is advantageously between 50 and 120 mm. Between the end of the quartz rod 9 facing away from the UV lamp 2 and the admission area 30 to the optical fibres, there is advantageously a cut-on filter 10 which shades out the short-waved UV radiation < 280 nm, since this causes a more rapid ageing of the optical fibres 3. The cut-on filter additionally prevents polymer degradation of the lens material. The cut-on filter 10 is suitably a WG 305 or 295 filter from the company Schott. Furthermore, a diaphragm 11 is provided between the cut-on filter 10 and the optical fibre admission area 30. By adjusting the aperture 12 of the diaphragm 11, the intensity of radiation entering the optical fibre 3 can be regulated. To regulate the coupled light intensity, the distance between the optical fibre

admission area 30 and the quartz rod 9 can also be modified. If a high UV intensity is desired, the distance should be as short as possible. In particular, there may be provisions for the diaphragm aperture 12 to be controlled via a stepping motor unit 13 which is linked to the diaphragm 11 in particular by a flexible coupling 14, whereby adjustment of the diaphragm aperture 12 can be regulated by the measurement of light intensity using a suitable UV measuring unit 15 at the light exit. There should be provision in particular for the diaphragm 11 of each optical fibre 3 to be adjustable independently. As well as solving this by means of a stepping motor unit, the diaphragms 11 may also be controlled manually if desired. The optical fibres 3 emerge from the housing 16 and are respectively arranged over a casting mould 17.

Fig. 3 depicts the exposure of a casting mould 17 consisting of a lower mould half 18 and an upper mould half 19. Arranged between the end of an optical fibre 3 and the upper mould half 19 is preferably a UV condenser 20, which consists of tempered quartz lenses. The condenser 20 serves to bundle the emitting ray of light. The optics thereof are co-ordinated with the geometry of the casting mould. In order to produce a contact lens which is polymerised throughout and has good quality of the edges, the distances between the end of the optical fibre 3 and the condenser 20 and between the condenser 20 and the upper mould half 19 are crucial. In addition, for an optimum path of rays, a diaphragm must be provided in the upper mould half 19. If the distance between the condenser 20 and the casting mould 17 is increased, the intensity of radiation is reduced. This leads to slower polymerisation of the lens material. However, if there is constant exposure time and the intensity of radiation is too high, the contact lenses become brittle and the quality of the edges of the contact lenses deteriorates. When selecting the distance between the condenser 20 and the upper mould half 19, an optimum setting must be found, which also depends on the geometry of the upper mould half. This distance is suitably between 30 and 5 mm.

In this way, by coupling the UV light into the mould cavity using optical fibres, the invention enables the mould cavity to be illuminated evenly. By coupling a number of optical fibres to a UV lamp, a very high and even intensity of illumination can be attained in an efficient manner, so that it is possible to polymerise the introduced moulding material very rapidly.

What we claim is

1. UV illuminating device for crosslinking biocompatible, polymerisable material in order to produce an ophthalmic moulding, especially an ophthalmic lens, in particular a contact lens, which is produced by crosslinking with UV light in a casting mould consisting of two mould halves, **characterised by** one or more UV lamps which are each surrounded by several optical fibres, whereby the optical fibres transmit the light emitting from the UV lamp to one or more casting moulds.
2. UV illuminating device according to claim 1, whereby an optical fibre is linked to a casting mould.
3. UV illuminating device according to claim 1 or claim 2, whereby the UV lamp in question is a mercury lamp.
4. UV illuminating device according to claim 3, whereby the UV lamp in question is a doped mercury lamp.
5. UV illuminating device according to one or more of claims 1 to 4, whereby the optical fibres in question are liquid optical fibres.
6. UV illuminating device according to one or more of claims 1 to 5, whereby the emission spectrum of the UV lamp has a high UV intensity at 280 - 360 nm.
7. UV illuminating device according to one or more of claims 1 to 6, whereby a sensor measuring the radiation intensity of the UV lamp is provided and connected to a regulating unit to regulate the UV radiation.
8. UV illuminating device according to one or more of claims 1 to 7, whereby a measuring unit is provided to measure the emitting UV radiation intensity.
9. UV illuminating device according to one or more of claims 1 to 8, whereby in order to couple in the UV radiation, a quartz rod is respectively provided between the UV lamp and the light admission area of the optical fibre.

10. UV illuminating device according to claim 9, whereby a cut-on filter is provided between the quartz rod and the optical fibre in order to absorb short-waved UV radiation.

11. UV illuminating device according to claim 10, whereby a WG 305 is provided as the cut-on filter.

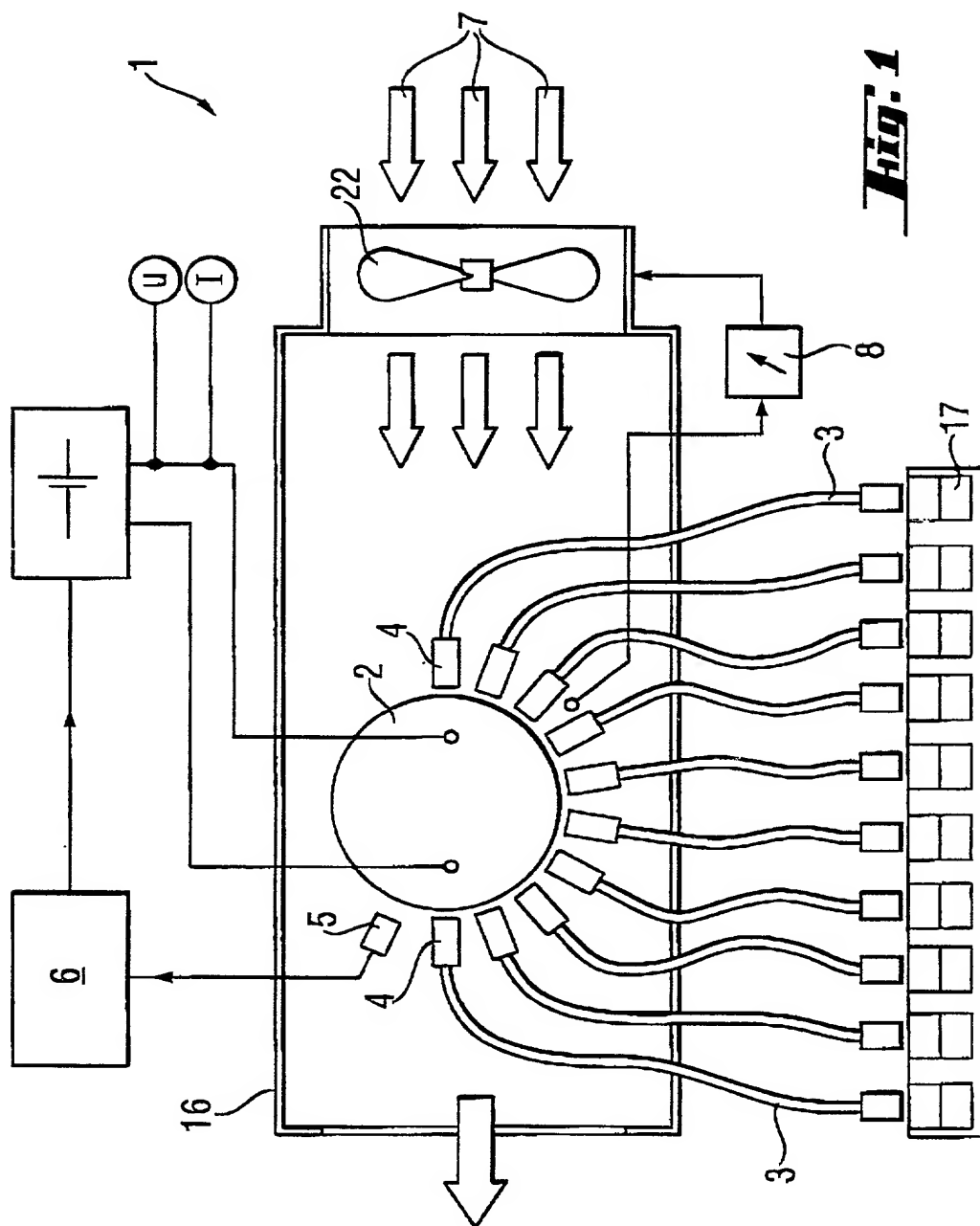
12. UV illuminating device according to one or more of claims 1 to 11, whereby a diaphragm is provided between the optical fibre and the UV lamp.

13. UV illuminating device according to claim 12, whereby the aperture of the diaphragm is adjusted by means of a stepping motor unit.

14. UV illumination device according to one or more of claims 8 to 13, whereby the aperture of the diaphragm is controlled in accordance with the measurement of UV radiation intensity being emitted.

15. UV illuminating device according to one or more of claims 1 to 14, whereby a UV condenser is mounted between the optical fibre and the mould half.

16. UV illuminating device according to one or more of claims 1 to 15, whereby the optical fibres are arranged radially around the UV lamp in relation to the longitudinal axis of the UV lamp.



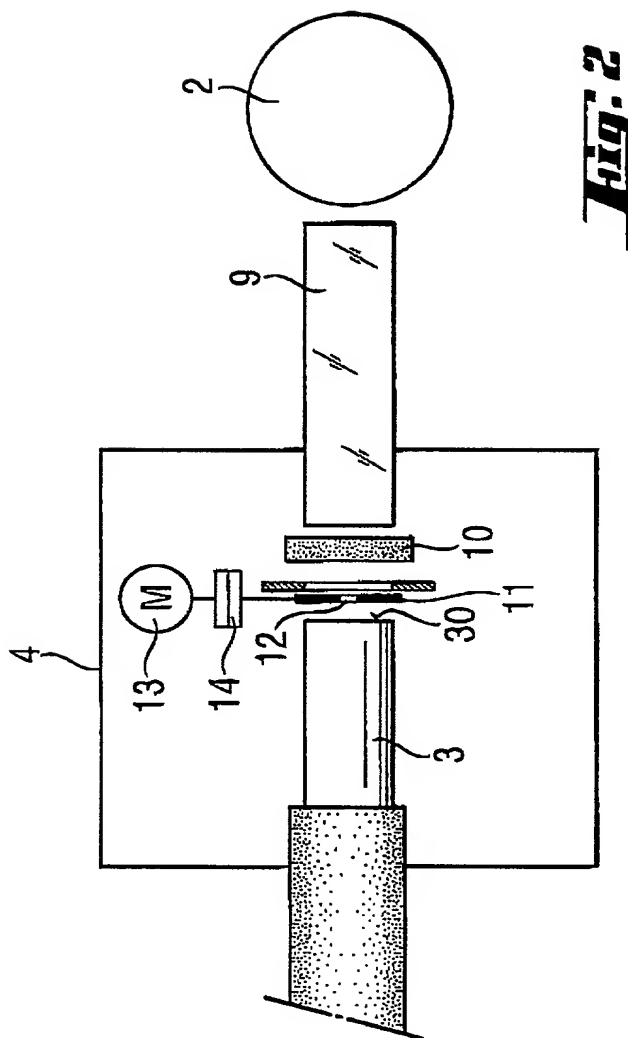


Fig. 2

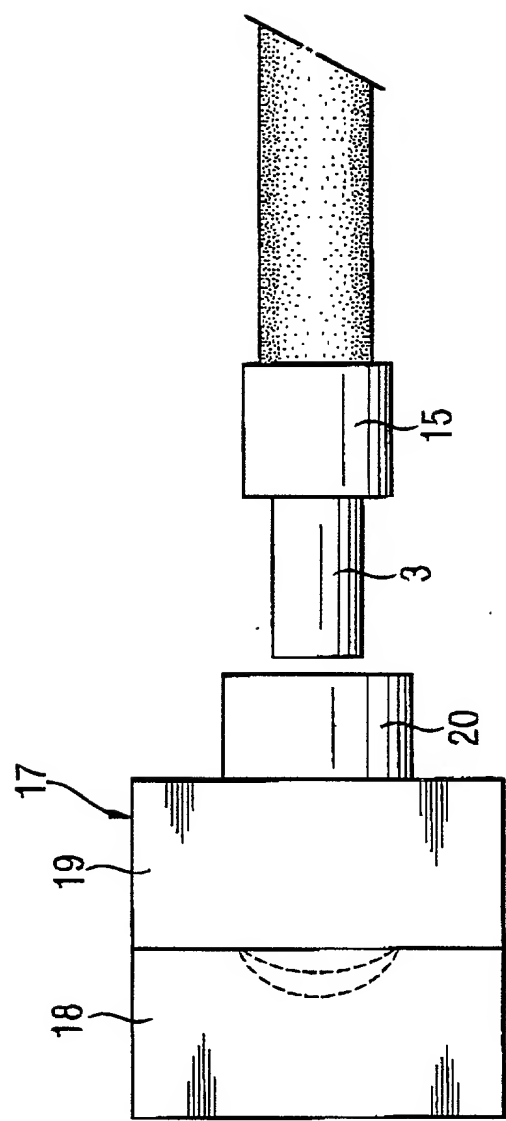


Fig. 3

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION

☒ Original

☐ Supplemental

☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

UV-illumination device

the specification of which:

☐ is attached hereto.

☐ was filed on _____ as Application No. _____
(day/month/year)

and, if this box (☐) contains an *

☐ was amended on _____
(day/month/year)

☒ was filed as Patent Cooperation Treaty international Application No.

PCT/EP 00/05835 on 23/06/2000
(day/month/year)

and, if this box (☐) contains an *

☐ entered the national stage in the United States and was accorded Application No. _____

and, if this box (☐) contains an *

☐ was amended, subsequent to entry into the national stage, on _____
(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose all information which is known by me to be material to the patentability of this application as defined in 37 C.F.R. § 1.56.

I hereby appoint the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If these brackets contain an X [X], I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from the Patents and Trademarks Division of Novartis Pharma AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please address all communications to the address associated with Customer No. 001095, which is currently Thomas Hoxie, Novartis Corporation, Patent and Trademark Department, 564 Morris Avenue, Summit, NJ 07901-1027.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole
or first joint inventor

Axel HEINRICH

Inventor's signature

Axel Heinrich

Date

14/11/01

(day/month/year)

Residence

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Citizenship

German

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Germany**

IMPORTANT: Before this declaration is signed; the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

200
Full name of second
joint inventor, if any

Achim MÜLLER

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Achim Müller

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14/11/01

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I hereby claim the benefit under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate listed below and under 35 U.S.C. §365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent or inventor's certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED	
(European Patent Applic.)	99112256.5	25/06/1999	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. § 119 (e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) listed below and under 35 U.S.C. §365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in said prior application(s) in the manner required by the first paragraph of 35 U.S.C. §112, I acknowledge my duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date(s) of the prior application(s) and the national or Patent Cooperation Treaty international filing date of this application:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date (day/month/year)